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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,927	04/10/2002	Jurgen Stoltefuss	LE A 33 783	8267
35969	7590	02/04/2004	EXAMINER	
JEFFREY M. GREENMAN BAYER PHARMACEUTICALS CORPORATION 400 MORGAN LANE WEST HAVEN, CT. 06516			BERNHARDT, EMILY B	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,927

Applicant(s)

STOLTEFUSS ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 10-15, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-14 and 19 is/are allowed.
- 6) ☒ Claim(s) 1-6 and 20 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Applicants are advised that the amendments to the specification have not been entered since the requested changes to the text appearing on p.7, 11 and 14 are not in conformance with recent changes made to Amendment Practice. See OG Notice of 23 September 2003. Additionally, the replacement tables for pages 30 and 32 were inadvertently not scanned into the electronic filing system (EDAN) and thus should be resubmitted in applicants' next response.

Applicants' amendments to the claims overcomes the 112 rejections of the previous action. The insertion of species previously provisoed out has been noted and its inclusion justified by the error applicants discuss in their response. It is noted that said species was originally covered by the method claims. The 103 rejection over Curran in view of March is withdrawn in view of applicants' discussion of the biological data reported in Curran as discussed on pp.32-33 of applicants' response. However the following new rejection is applied.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over McEvoy in view of March. McEvoy is consecutive to the Curran article previously applied. The examiner's copy of Curran contains McEvoy as well but is additionally provided to applicants herewith. The journal article from the same

research company as Curran describes a compound very similar to that claimed herein for use as an antihypertensive agent. See compound no.56 in Table I. Note said compound is not the same compound as eg.18 in Curran as it has a methyl group at the 5-position of the dihydropyridazinone ring. Said compound differs from closest instant compounds only in being unsubstituted vs. 1 (previously excluded) or 2 Me groups on the carboxamide nitrogen and thus are obvious variants for the same reason given previously. The Doebel and Weston decisions are still believed on point notwithstanding applicants' attempt to distinguish these cases from the present fact situation. In Doebel the court upheld the rejection with the following quote (at p.160): "We agree with the examiner that the striking structural similarity of the compounds of claim 1 to promazine and chlorpromazine suggests to workers of ordinary skill in pharmaceutical chemistry that the claimed compounds would have some tranquilizing properties." In Weston while an admission of equivalency for H and alkyl in the original disclosure was present, this was not the sole criterion for refusing claims. Note the comment made on p.429, right column: "We are satisfied that appellants' compound is the next obvious homolog of the compounds shown by Baltzly et al." This rationale is consistent with the later Doebel decision pointed out above as well with a long line of cases that deal solely with close structural similarity without an

express teaching to modify. See *In re Wood* 199 USPQ 137; *In re Lohr* 137 USPQ 548; *In re Fauque* 121 USPQ 425 for legal authority in determining obviousness based on close structural similarity. With regard to the designation of such methylated analogs as homologs by the Court in *Weston*, note *In re Payne* 203 USPQ 245 (and the many decisions which cite *Payne*) in which it is stated that "the name used to designate the relationship between related compounds is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound." Thus in the absence of comparative results with said compound and instant compounds pointed out above which show a patentable distinctness for instant N-methylated analogs for use relied on herein, this rejection will be maintained. Note also that compound **56** is particularly addressed as having a potent antihypertensive effect. See p. 284.

The process of claim 5 and 20 are also rendered obvious in view of the teachings of March as previously discussed. Note that acid halides including chlorides, particularly claimed in claim 20, are obvious expedients to making carboxamides. In fact applicants admit that starting material sources such as formula IV are well known in the art or can be prepared by conventional routes .

Thus, the instant situation is unlike Ochiai or Brouwer cited by applicants since final products made by the process of claims 5 and 20 are obvious for the reasons discussed above and the reactants are also old.

Claims 10-14 and 19 are allowed.

Claim 15 is objected to for containing a typo. Note the word "anemis" rather than "anemias".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is (703)308-4714.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.



Emily Bernhardt
Primary Examiner
Art Unit 1624